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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,029	07/24/2001	Gabor Bogye	21965	6045

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,029	BOGYE, GABOR	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-12,20 and 25-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12,20 and 25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office action will replace the previous mailed office action dated April 27, 2006.

Claims 26-39 have been added. Claims 13-19 and 21-24 have been cancelled.

The declaration filed February 9, 2006 have been considered, and is not found persuasive to withdraw the rejection under 35 USC 102(e) over Kafrissen et al. Examiner notes that in affidavit under 37 CFR 1.131 cannot obviate rejection under 35 USC 102(e), when the cited prior arts is a US Patent (See MPEP 706.02(b) (D)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 26-28, 32, 33, 34,35, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "an otherwise healthy patient" recited in claim 20 renders the claims indefinite as to the patient population encompassed thereby. It is not clear what patients or individually would be considered "healthy" as recited in the claims. Is patients experiencing side effect from the medication considered "healthy"? For example, if a patient takes progesterone composition and experience headache or depression after taking the medication, is she a "healthy" patient? The metes and bounds of the claims are not clear. Furthermore, are they otherwise healthy if no

medication was taken (including the hormonal composition)? Or does the term mean that the patients are healthy if no plasma homocysteine reducing agents are taken?

Claim 39 recites the limitation "for contraception" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Applicant's arguments filed February 9, 2006 averring the term being understood by one of ordinary skill in the art, by citing various literatures, have been considered, but are not found persuasive. The term in question is crucial to the interpretation of the claims and the rejection set forth in the previous office actions. It is clear that the instant specification does not provide any definitions of such expression and that such expression can be at least interpreted into more than one valid meanings. Therefore, the metes and bounds of the claims is therefore, can not be ascertained by one of ordinary skill in the art.

Examiner notes that the term "otherwise healthy patient" is interpreted as individual who is healthy without taking the hormonal composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 28, 29, 31, 32, 33, 35, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Spellacy et al. (Contraception, 1972;6(4):263-273), reference of record.

Spellacy et al. teaches vitamin B6 supplement is administered to women taking progesterone containing oral contraceptive (See the abstract).

Claims 20, 27, 32, 33, 34, 35, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Butterworth et al. (Am. J. Clin. Nutr., 1982;35(1):73-82 from IDS received 1/2/2002).

Butterworth et al. teaches folic acid was supplemented to women taking progesterone containing oral contraceptive (See the abstract).

Claims 9, 11, 20, 27, 32-36, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Kafrissen et al. (US Patent 6,190,693).

Kafrissen et al. teaches a method of administering folic acid along with either oral contraceptives containing progesterone or hormone replacement therapy containing progesterone (See for example claims 5 and 8). Kafrissen et al. also teaches the amount of folic acid employed as 25microgram to 1gram to reducing homocyteine level (See col. 7, lines 55-56).

Response to Arguments

Applicant's arguments filed February 9, 2006 averring Spellacy's failure to teach healthy patients have been considered, but are not found persuasive. The term "otherwise healthy patients" is interpreted as individual who is healthy without taking the hormonal composition. In Spellacy, patients taking steroidal contraceptions inducing the carbohydrate metabolism disorders; therefore, without taking steroidal compositions, the patient would be healthy. Accordingly, the patient population is considered the same as recited, which is "otherwise healthy" population.

Applicant's arguments filed February 9, 2006 averring Spellacy's failure to teach the administration of vitamin B6 in combination with a gestagen hormone to reduce the risk of thromboembolism have been considered, but are not found persuasive. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent

examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Applicant's arguments filed February 9, 2006 averring Butterworth failure to teach healthy patients have been considered, but are not found persuasive. The term "otherwise healthy patients" is interpreted as individual who is healthy without taking the hormonal composition. In Butterworth, patients taking steroidal contraceptions inducing cervical dysplasia; therefore, without taking steroidal compositions, the patient would be healthy. Accordingly, the patient population is considered the same as recited, which is "otherwise healthy" population.

Applicant's arguments filed February 9, 2006 averring Butterworth's failure to teach the administration of folic acid in combination with a gestagen hormone to reduce the risk of thromboembolism have been considered, but are not found persuasive. See the inherency arguments presented above.

Applicant's arguments filed February 9, 2006 averring Kafrissen's failure to teach the same patient population have been considered, but are not found persuasive. Examiner notes that the patients are the same as patient population recited herein. Since they are taking gestagen hormone for either contraception or hormone replacement therapy; and at the same time, they are taking folic acid, in the herein

claimed dosage, for the reasons of reduction of elevated homocysteine levels. Furthermore, Applicant argues that the patients in Kafrisen are ill or they have risk factor before taking gestagen hormone. Such arguments have been considered, but are not found persuasive since the arguments are directed to unclaimed limitations. In additions, having risk factor does not clinically mean the patients are ill. For example, being a male at age more than 65 is one of the risk factor for prostate cancer, but being age of 65 and male does not necessarily means that the individual is ill or having abnormality. Applicant's logic is flawed. There are no imitations directed to the state of health of the patients before taking gestagen hormone recited in the claims. Therefore, whether patients in Kafrissen are having abnormality or not is immaterial and moot.

Applicant's arguments filed February 9, 2006 averring the patients populations in Kafrissen being excluded in the instant application have been considered, but are not found persuasive. The references cited in page 20 cannot be a probative evidence to define what is claimed since the specification does not even define what the term "otherwise healthy patients" might be. In the instant specification, most of the examples disclosed are directed to healthy patients; however, in example d) women are using gestagen in fertilization program. Individual who are in fertilization is not considered healthy because they are having problem conceiving. Moreover, patient population disclosed in page 5 is directed to patients suffered with overweight, which are not healthy population.

Applicant's arguments filed February 9, 2006 with regard to Kafrisen's teachings, stating "it is not at all obvious that a treatment suggested for a certain population (i.e., a

population whose members are afflicted with, or predisposed to become afflicted with, a disorder are a higher-than normal incidence" have been considered, but are not found persuasive. Examiner notes that the claims do not even excluded any non-healthy patients (See the discussion above with regard to patients in fertilization program and overweight patients). The arguments are hinges on the definition of the term "otherwise healthy patients", in which the instant specification is failed to define. Therefore, as discussed above, Examiner construed the term as "otherwise healthy patient" is interpreted as individual who is healthy without taking the hormonal composition. In Kafrissen, individual who takes oral contraceptive and folic acid, can be one that is predisposed to become afflicted with (i.e., having the risk factors) a disorder. It is clear that the individual does not necessarily been afflicted with the disorder. She only has the risk factor. As discussed above, having the risk factors of a disease is not equal to having the disease itself. In view of the discussion, the instant claims are still considered properly rejected under 35 USC 102(e) over Kafrissen.

Applicant's remarks with regard to the 37 CFR 1.131 declaration have been considered, but are not found persuasive to withdraw the rejection under 35 USC 102(e) (See discussion above and MPEP 706.02(b) (D)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12, 20, and 25-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Patent 5,654,011) in view of Fermo et al. (Annals of Internal Medicine, 1995:123(10):747-753 – html version).

Jackson et al. teaches a multivitamin composition containing homocysteine level reduction amount of folic acid, vitamin B6, and vitamin B12 (See col. 3, line 60-63, col. 5, lines 15-30, col. 6, lines 18-21). Jackson's composition is taught as useful inn various stages of women life for reducing health risks of women (See the abstract).

Jackson et al. does not expressly teach the patients taking hormonal composition containing gestagen.

Fermo et al. teaches hyperhomocysteinemia as pathogenic significant of patients developing thrombosis (See the abstract and the Discussion Section).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition.

One of ordinary skill in the art would have been motivated to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition. It is known that high homocysteine level is associated with coronary diseases including thrombosis. Therefore, employing a homocysteine reducing amount of vitamin B6, B12, and folic acid, regardless of what the cause of hyperhomocysteinemia or patient population might be, to any patient suffering from hypercysteinemia including patient population herein recited, would be reasonably expected to be useful and effective in lowering the homocysteine level and further reducing the risk of thrombosis thereby.

Response to Arguments

Applicant's arguments filed February 9, 2006 averring the cited prior art's failure to disclose the administration of gestagen hormone and its relationship between homocysteins levels and thromboembolism have been considered, but are not found persuasive. The herein claimed invention is directed towards the treatment of elevated homocysteine levels in order to reduce the risk of thromboembolism using old and well-known agents for reducing homocysteine levels due to gestagen hormone. Examiner notes that the herein claimed agents are known to decrease the level of homocysteine, which is responsible for increasing the risk of cardiovascular disorders. Therefore, one of ordinary skill in the art would have been motivated to employ the herein recited agents to treat the elevated homocysteine levels and thereby reduce the risk of thromboembolism in the same patients, regardless of the cause of elevated

homocysteine level. Considering the following example: morphine, an old and well-known analgesic, is known to be effective to treat pain, regardless of what the causes might be, be it cancer related pain, pain due to broken bone, or pain due to kidney stone. These conditions can be effectively treated with morphine since the treatment is directed to pain itself not the etiologies of it. In the same way, the instant invention is to treat elevated homocysteine levels, not the etiologies (e.g., one of which is gestagen hormone according to the instant claim) of it. Therefore, when a patients is presented with elevated homocysteine levels, possessing the cited prior arts, one of ordinary skill in the art would have employed the herein claimed agents in a method of treting hyperhomocysteinemia and thereby reducing the risk of thromboemolism.

Applicant's arguments filed February 9, 2006 averring the herein claimed agents, e.g., folic acid, vitamin B6, or vitamin B12, not being known to reduce the risk of thromboembolism when taken with gestagen hormone have been considered, but are not found persuasive. The reasons of the rejection is based on the fact that these agents are well known to be useful in decreasing homocysteine levels and thereby reducing the risk of thromboembolism.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617